

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Officer	<i>D. Hawkins</i>

[Docket No. 98N-0044]

Small Entity Compliance Guide: "Structure/Function Claims;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in **the Federal Register** of January 6, 2000 (65 FR 1000), entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect on the Structure or, Function of the Body." This SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments concerning this SECG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the SECG to the Industry Activities Staff (HFS-565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Robert Moore, Center for Food Safety and Applied Nutrition (HFS-81 1), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. 202-205-4605, FAX 202-205-4594.

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SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 6, 2000 (65 FR 1000), FDA issued a final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The regulation also established criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. The final rule clarified the types of claims that may be made for dietary supplements without prior review by FDA and the types of claims that require prior authorization as health claims or prior approval as drug claims. This final rule became effective February 7, 2000.

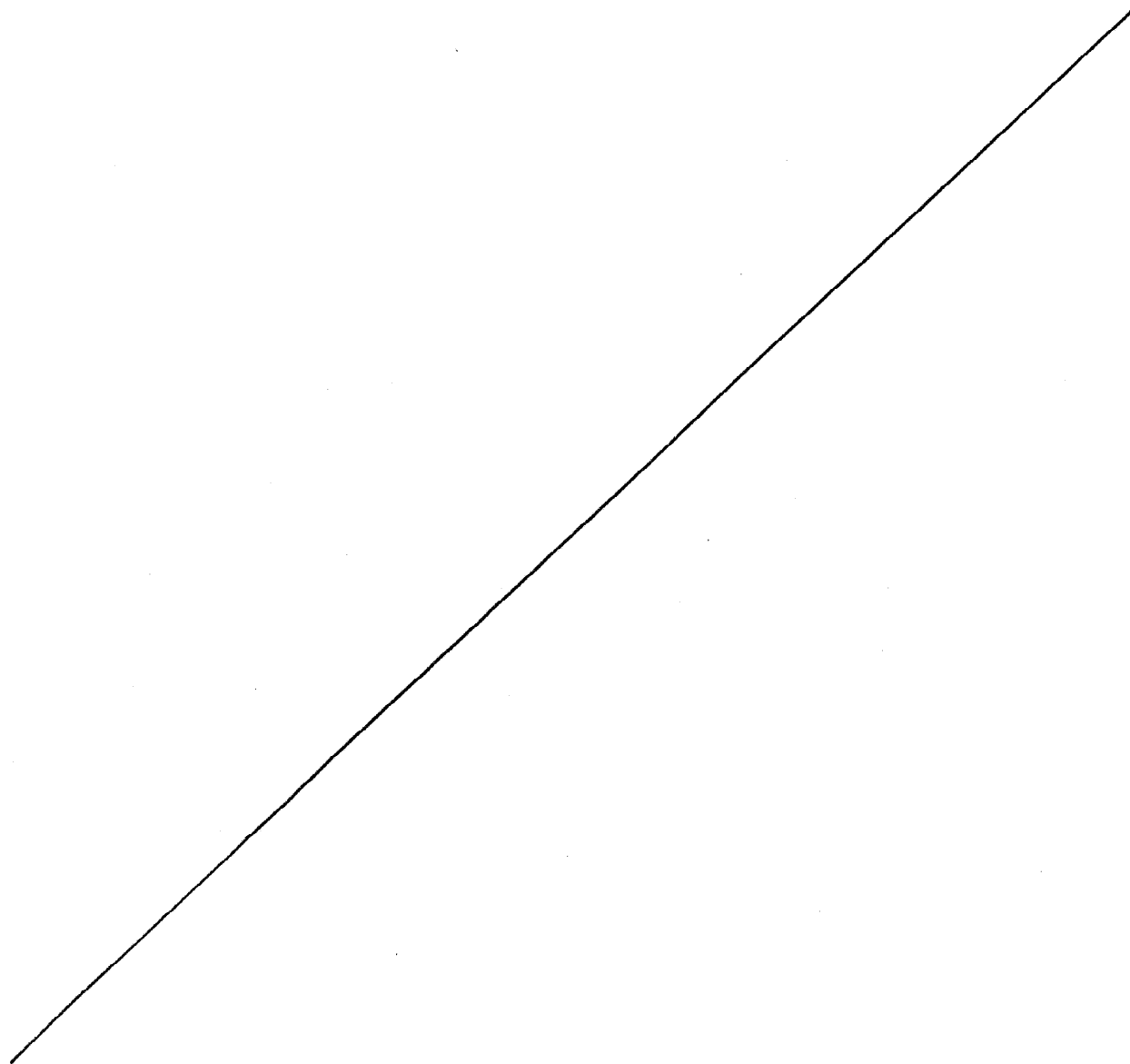
FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602). The agency determined that the final rule would have a significant economic impact on a substantial number of small entities.

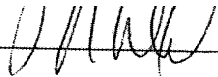
In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the requirements of this regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency’s current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the SECG entitled “Structure/Function Claims; Small Entity Compliance Guide” to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the SECG and received comments are available for




Margaret M. Dotzel,
Associate Commissioner for Policy.

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Dora P. Hawkins